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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,414	06/23/2003	David James Dooley	PC9997A	9185
28880	7590	09/19/2006	EXAMINER	
WARNER-LAMBERT COMPANY			WANG, SHENGJUN	
2800 PLYMOUTH RD				
ANN ARBOR, MI 48105			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 09/19/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/602,414

Applicant(s)

DOOLEY, DAVID JAMES

Examiner

Shengjun Wang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 6-23 and 26-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 8-23, 38-45, 53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, Claims 6, 7, 24-37, 46-52, 54 and 55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 12, 2006.
2. Applicant's election with traverse of invention group I and pregabalin as the active compound in the reply filed on July 12, 2006 is acknowledged. The traversal is on the ground(s) that the compounds are all alpha2delta ligand. This is not found persuasive because the patentability of the claims is based on whether the compounds has been used, or would have been obvious to be used for treatment of ADHD, regardless of alleged functions of the compounds.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on elected invention and species.

#### ***Claim Rejections 35 U.S.C. 103***

- a. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
3. Claims 1-5, 24, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dewey et al. (US 6,462,084), in view of Silverman et al. (IDS) and Dooley et al. (IDS).

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4. Dewey teaches a method of treating compulsive disorder or compulsive related disorders comprising administering to a patients gamma vinyl GABA (GVG), or other GABA agonists, or compounds that potentiate the GABAergic system, or increase extracellular endogenous GABA level, such as gabapentin, etc. Compulsive disorders therein are defined as to include attention deficit hyperactivity disorder (ADHD). See, particularly, the abstract, col. 2, line 46 to col. 3, line 7, col. 5, line 7 to col. 6, line 5.

5. Dewey et al. do not teach expressly the employment of pregabalin for treatment of ADHD.

6. However, as revealed by Silverman et al. and Dooley et al. it is known in the art that pregabalin and gabapentin have similar pharmacology and are known to be similarly useful as therapeutical agents. See, particularly, the abstract, col. 2, lines 35-55 in Silverman et al. and the paragraph bridging pages 1086 and 1087 in Dooley et al.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ pregabalin as a GABAergic compounds for treating ADHD.

A person of ordinary skill in the art would have been motivated to employ pregabalin as a GABAergic compounds for treating ADHD because pregabalin is known to be similarly useful as gabapentin.

7. Claims 1-5, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamrin et al. (IDS) in view of Silverman et al. (IDS) and Dooley et al. (IDS).

8. Hamrin et al. teach an effective method of treating patient suffering ADHA with gabapentin. See, particularly, the abstrac.

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9. Hamrin et al. do not teach expressly the employment of pregabalin for treatment of ADHD.

10. However, as revealed by Silverman et al. and Dooley et al. it is known in the art that pregabalin and gabapentin have similar pharmacology and are known to be similarly useful as therapeutical agents. See, particularly, the abstract, col. 2, lines 35-55 in Silverman et al. and the paragraph bridging pages 1086 and 1087 in Dooley et al.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to substitute gabapentin with pregabalin in the method for treating ADHD.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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~~SHENGJUN WANG~~  
~~PRIMARY EXAMINER~~

Shengjun Wang  
Primary Examiner  
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